

MLN Matters Number: MM5404

Related Change Request (CR) #: 5404

Related CR Release Date: November 24, 2006

Effective Date: January 1, 2007

Related CR Transmittal #: R1115CP

Implementation Date: January 2, 2007



Do you have your NPI? National Provider Identifiers (NPIs) will be required on claims sent on or after May 23, 2007. Every health care provider needs to get an NPI. Learn more about the NPI and how to apply for an NPI by visiting <http://www.cms.hhs.gov/NationalProvIdentStand/> on the CMS web site.

## New Waived Tests

### Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare carriers and/or Part A/B Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries.

### Provider Action Needed

This article is based on Change Request (CR) 5404 which informs carriers and A/B MACS of new waived tests approved by the Food and Drug Administration (FDA) under Clinical Laboratory Improvement Amendments of 1988 (CLIA).

### Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test they perform. Laboratory claims are currently edited at the CLIA certificate level in order to ensure that the Centers for Medicare & Medicaid Services (CMS) only pays for laboratory tests categorized as waived complexity under CLIA (for facilities with a CLIA certificate of waiver).

New waived tests are approved by the FDA on a flow basis, and the tests are valid as soon as they are approved. The new waived tests announced by CR5404 are in the following table:

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

Newly Added CLIA Waived Tests	Effective Date	Current Procedural Terminology (CPT) Code(s) / Modifier
Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test	June 15, 2006	82274QW, G0328QW;
Gryphus Diagnostics BVBlue	June 30, 2006	87899QW
ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)	September 18, 2006	83655QW.

**Note:** The Current Procedural Terminology (CPT) codes for these new waived tests must have the modifier QW to be recognized as a waived test. Also, for 2007, the new CPT/HCPCS code 87808QW (Infectious agent antigen detection by immunoassay with direct optical observation; *Trichomonas vaginalis*) replaces the code 87899QW that was assigned to the Genzyme OSOM *Trichomonas* Rapid Test.

## Additional Information

For complete details, please see the official instruction, CR5404, issued to your carrier or A/B MAC regarding this change. That instruction may be viewed at <http://www.cms.hhs.gov/transmittals/downloads/R1115CP.pdf> on the CMS web site. The attachment to CR 5404 includes the list of tests granted waived status under CLIA, and the tests mentioned on the first page of the attachment (i.e., CPT codes: 81002, 81025, **82270**, 82272, **G0394**, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

As mentioned in Change Request 5292 (Transmittal 1062, dated September 22, 2006), the HCPCS code **G0107** (Colorectal Cancer Screening; fecal-occult blood test, 1-3 simultaneous determinations) will be retired effective January 1, 2007 and has been replaced with CPT code 82270 [Blood, occult, by peroxidase activity (e.g., Guaiac) qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided three cards or single triple card for consecutive collection)].

For 2007, the new CPT/HCPCS code **G0394** is for Blood occult test (e.g., guaiac), feces, for single determination for colorectal neoplasm (i.e., patient was provided three cards or single triple card for consecutive collection). This code does not require a QW modifier.

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To view CR5292 (Transmittal 1062, dated September 22, 2006), please go to <http://www.cms.hhs.gov/Transmittals/downloads/R1062CP.pdf> on the CMS web site.

The MLN Matters article based on CR5292 is located at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5292.pdf> on the CMS web site.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS web site.

### Flu Shot Reminder

Flu season is here! Medicare patients give many reasons for not getting their flu shot, including—"It causes the flu; I don't need it; it has side effects; it's not effective; I didn't think about it; I don't like needles!" The fact is that out of the average 36,000 people in the U.S. who die each year from influenza and complications of the virus, greater than 90 percent of deaths occur in persons 65 years of age and older. You can help your Medicare patients overcome these odds and their personal barriers through patient education. Talk to your Medicare patients about the importance of getting their annual flu shot--and don't forget to immunize yourself and your staff. **Protect yourself, your patients, and your family and friends. Get Your Flu Shot.** Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. For more information about Medicare's coverage of adult immunizations and educational resources, go to CMS's web site:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0667.pdf>

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